I hereby certify that this correspondence is being electronically filed in the United States Patent and Tyademark Office on July 29(2011.)

RESPONSE TO DECISION Docket No. TPI.5053C3XC1T

Frank C. Eisenschenk, Ph.D., Patent Attorney

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Art Unit : 1626

Applicants : Magali Bourghol Hickey, Matthew Peterson, Örn Almarsson, Michael J.

Zaworotko, Tanise Shattock, Jennifer McMahon, Joanna Bis, Julius F.

Remenar, Mark Tawa

Serial No. : 10/599,010

Filed: Scptcmber 18, 2006

Conf. No. : 3133

For : Novel Pharmaceutical Forms, and Methods of Making and Using the Same

Mail Stop PETITION Commissioner for Patents Office of PCT Legal Administration P.O. Box 1450 Alexandria, VA 22313-1450

RESPONSE TO DECISION

Sir:

A Decision was received from the Patent and Trademark Office on July 5, 2011 in the above-referenced patent application indicating that the Notification of Acceptance mailed August 1, 2007 was vacated because the Declaration did not comply with 37 CFR 1.497(a)-(b). Transmitted herewith is a fully executed Declaration (37 CFR § 1.63) for Utility or Design Application Using an Application Data Sheet form for the subject application executed by all the inventors, along with a Supplemental Application Data Sheet.

The Decision also indicates that the Petition Under 37 C.F.R. 1.48(b) filed on November 9, 2007 has not been acted on at this time. By way of this response, Applicants respectfully request consideration of the Petition in due course.

The Commissioner is authorized to charge any fees that may be required by this paper to Deposit Account No. 19-0065.

Respectfully submitted,

Frank C. Eisenschenk, Ph.D.

Patent Attorney

Registration No. 45,332

Phone No.: 352-375-8100 Fax No.: 352-372-5800 Address: P.O. Box 142950

Gainesville, FL 32614-2950

FCE/jb/sl

Attachments: Executed Declaration

Supplemental ADS

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless if displays a valid CMB control number

DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

| Title of Invention | Novel Pharmaceutical Forms, and Methods of Making and Using the Same | | |
|---------------------------|---|--|--|
| As the belo | w named inventor(s), I/we declare that: | | |
| This declar | ation is directed to: | | |
| | The attached application, or | | |
| | Application No. <u>PCT/US2005/009305</u> , filed on <u>MARCH 17, 2005</u> , | | |
| | as amended on 9/18/2006; 7/23/2008 (if applicable), | | |
| I/we believe sought; | that I/we am/are the original and first inventor(s) of the subject matter which is claimed and for which a patent is | | |
| I/we have re amendment | eviewed and understand the contents of the above-identified application, including the claims, as amended by any specifically referred to above; | | |
| material to became av | I/we acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me/us to be material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT International filing date of the continuation-in-part application. | | |
| to be true, a | nts made herein of my/own knowledge are true, all statements made herein on information and belief are believed and further that these statements were made with the knowledge that willful false statements and the like are by fine or imprisonment, or both, under 18 U.S.C. 1001, and may jeopardize the validity of the application or any any thereon. | | |
| FULL NAME | OF INVENTOR(S) | | |
| Inventor one | : _MAGALI BOURGHOL HICKEY | | |
| Signature: 』 | Mayol & Wille Cilizen of: UNITED STATES | | |
| | : MATTHEW PETERSON | | |
| Signature: _ | Cilizen of: _UNITED STATES | | |
| Inventor thre | e: ORM ALMARSSON | | |
| Signature: _ | Citizen of: ICELAND | | |
| Inventor four | MICHAEL J. ZAWOROTKO | | |
| Signature: | Citizen of; UNITED KINGDOM | | |
| Addition | onal inventors or a legal representative are being named on 1 (one) additional form(s) attached hereto | | |

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to cotain or retain a benefit by the public which is to file (and by the USPTO to process) an application Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the incividual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS, SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76) – continuation page

Title of Invention: Novel Pharmaceutical Forms, and Methods of Making and Using the Same

Signature: Mark Terre Citizen of: UNITED STATES

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| this neclar | ation is directed to: | | |
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| full mild and market ma | Application No. PCT/US2005/009305 , filed on MARCH 17 2005 | | |
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| Vwe believe sought: | that I/we am/are the original and first inventor(s) of the subject matter which is claimed and for which a patem is | | |
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| - (U DM HUM, U | onts made herein of my/own knowledge are true, all statements made herein on information and belief are believed and further that these statements were made with the knowledge that willful faise statements and the like are by fine or imprisonment, or both, under 18 U.S.C. 1001, and may jeopardize the validity of the application or any ag thereon. | | |
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| | OF INVENTOR(S) | | |
| | MAGALI BOURGHOL HICKEY | | |
| Signature | Citizen of UNITED STATES | | |
| Inventor two | MATTHEW PETERSON | | |
| Signature | Mattin Later Of UNITED BLAVES | | |
| Inventor thre | e: ORN ALMARSSON | | |
| Signature: | Citizen of: ICELAND | | |
| | MICHAEL J. ZAWOROTKO | | |
| Signature | Citizen of UNITED KINGDOM | | |
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minute to compete including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon any ordered application form to the USPTO. Time will vary depending upon any ordered this form and/or suggestions for reducing this burden, should be sent to the Chair residence of USPTO Alexandria, VA 22313-1450, BO GOT SEND FLES OF HOMES. To be USPTO THE SEND FLES OF HOMES. TO BOX 1450, Afexandria, VA 22313-1450.

DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76) continuation page

Litle of Invention: Novel Pharmaceutical Forms, and Methods of Making and Using the Same Application No.: PCT/US2005/009305, filed on March 17, 2005 as amended on 09/18/2006: 07/23/2008

| threstor tre: TANISE SHATTOCK | |
|--------------------------------|---------------------------|
| Signature; | Citizen of: JAMAICA |
| Inventor six: JENNIFER McMAHON | |
| Signature: | Citizen of: UNITED STATES |
| | |
| Inventor seven: JOANNA BIS | |
| Signature: | Citizen of: POLAND |
| | |
| Inventor eight: JULIUS REMENAR | |
| Signature: | Citizen of: UNITED STATES |
| | |
| Inventor nine: MARK TAWA | |
| Signature: | Citizen of: UNITED STATES |

DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

| Title of Invention | Novel Pharr | naceutical Forms, and M | Methods of Making and Us | ing the Same |
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| I/we believe scur,ht; | e that Vwe am/are | the original and first inventor(s | i) of the subject matter which is cla | simed and for which a paters re |
| l/we have r amendmen | reviewed and under t specifically refer | erstand the contents of the abovered to above; | ve-identified application, including t | the claims, as amended by any |
| pactitue av | pateniability as d | letined in 37 CFR 1.55, including the filling date of the prior appl | Patent and Trademark Office all infig g for continuation-in-part application lication and the national or PCT | more proportional information as the contract |
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| Inventor two | : MATTHEW PETI | ERSON | over the contract of the contr | Medianaportoportoportoportopa sentina dendina con esta esta per per la compara esta esta esta esta esta esta e |
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Additional inventors or a legal representative are being named on 1 (one) additional form(s) attached hards.

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Title of Invention: Novel Pharmaeeutical Forms, and Methods of Making and Using the Same

Application No.: PCT/US2005/009305, filed on March 17, 2005

as amended on 09/18/2006; 07/23/2008

| Inventor five: TANISE SHATTOCK | |
|--------------------------------|---------------------------|
| Signature: | Citizen of: JAMAICA |
| Inventor six: JENNIFER McMAHON | |
| Signature: | Citizen of: UNITED STATES |
| Inventor seven: JOANNA BIS | |
| Signature: | Citizen of: POLAND |
| Inventor eight: JULIUS REMENAR | |
| Signature: | Citizen of: UNITED STATES |
| Inventor nine: MARK TAWA | |
| Signature: | Citizen of: UNITED STATES |

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| As the belo | w camed inventor(s). I/we declare that: | | |
| This declar | ation is directed to. | | |
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| | Application No PCT/US2505/009305 filed on MARCH 17, 2005 | | |
| | as amended on 9/18/2006; 7/23/2005 (if applicable): | | |
| t/we bollevo sought, | that I/we am/are the original and first inventor(s) of the subject matter which is claimed and for which a potent is | | |
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| Enventor on | e: MAGALI BOURGHOL HICKEY | | |
| | Citizen of UNITED STAIFS | | |
| inventor two | MATTHEW PETERSON | | |
| Signature: | Clizen of UNITED STATES | | |
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| | Citizen of: ICELAND | | |
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Signature: Citizen of: POLAND

Inventor eight: JULIUS REMENAR

Signature: Citizen of: UNITED STATES

Signature: _____ Citizen of: UNITED STATES

Inventor nine: MARK TAWA

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| Simplified. | Citizen of: JAMAICA |
| Inventor six: JENNIFER McMAHON Signature: JANAGE TO Ma | NEYT Citizen of: UNITED STATES |
| Inventor seven: JOANNA BIS | |
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| Inventor eight: JULIUS REMENAR Signature: | Cidzen of UNITED STATES |
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| Inventor nine: MARK TAWA | |
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| FULL NAM | E OF INVENTOR(S) | |
| Inventor or | e: MAGALI BOURGHOL HICKEY | |
| Signature: | Citizen of: UNITED STATES | |
| Inventor tw | o: MATTHEW PETERSON | |
| Signature: | Citizen of: UNITED STATES | |
| Inventor th | ree: ORN ALMARSSON | |
| Signature: | Citizen of: _ICELAND | |
| Inventor fo | ur: MICHAEL J. ZAWOROTKO | |
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| Signature: | Citizen of: JAMAICA |
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| Signature: | Citizen of: UNITED STATES |
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| Inventor nine: MARK TAWA | |
| Signature: | Citizen of LINITED STATES |

PTO/S8/81 (04-05)

Approved for use through 11/30/2005, OMB 0651-0035 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Ac; of 1995, no persons are require

POWER OF ATTORNEY and **CORRESPONDENCE ADDRESS INDICATION FORM**

| ed to respond to a collection of info | ormation unless it displays a valid CMB control number. |
|---------------------------------------|---|
| Application Number | 10/599,010 |
| Filing Date | September 18, 2006 |
| First Named Inventor | Magali Bourghol Hickey |
| Title | Novel Pharmaceutical Forms, |
| Art Unit | |
| Examiner Name | |
| Altiomey Docket Number | TPI-5053C3XC1T |

| I hereby revoke all previous powers of attorney give | I hereby revoke all previous powers of attorney given in the above-identified application. | | | | |
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| I hereby appoint: | | | | | |
| Practitioners associated with the Customer Number: | 23557 | | | | |
| Practitioner(s) named below: | | | | | |
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| as my/our attomey(s) or agent(s) to prosecute the application i Trademark Office connected therewith. | identified above, and to transact all busin | ness in the United States Patent and | | | |
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| lam the: | Cilian | | | | |
| Applicant/Inventor. | | | | | |
| Assignce of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Fcrm PTO/SB/96) | | | | | |
| SIGNATURE of Applicant or Assignee of Record | | | | | |
| Signature (200) | | Date Feb -23-7009 | | | |
| Name JOANNA BIS | | Telephone TW 75 | | | |
| Title and Company | | | | | |
| NOTE: Signatures of all the invantors or assigness of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below. | | | | | |
| *Total offorms are submitted. | | | | | |

This collection of information is required by 37 CFR 1.31, 1.32 and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this purden, should be sent to the Chief information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/81 (04-05)
Approved for use through 11/30/2005, OMB 0651-0035
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POWER OF ATTORNEY and CORRESPONDENCE ADDRESS INDICATION FORM

| Application Number | 10/599,010 | | |
|------------------------|-----------------------------|--|--|
| Filing Date | September 18, 2006 | | |
| First Named Inventor | Magali Bourghol Hickey | | |
| Title | Novel Pharmaceutical Forms, | | |
| Art Unit | | | |
| Examiner Name | | | |
| Attorney Docket Number | TPI-5053C3XC1T | | |

| I hereby revoke all previous powers of attorney gi | ven in the above-identified application. | | | |
|---|--|--|--|--|
| I hereby appoint: | | | | |
| Practitioners associated with the Customer Number: OR | 23557 | | | |
| Practitioner(s) named below: | | | | |
| Name | Registration Number | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| as my/our attorney(s) or agent(s) to prosecute the application Trademark Office connected therewith. | dentified above, and to transact all business in the United States Patent and | | | |
| Please recognize or change the correspondence address for t | ne above-Identified application to: | | | |
| The address associated with the above-mentioned C | | | | |
| OR | | | | |
| The address associated with Customer Number; | | | | |
| OR Firm or | | | | |
| individual Name | | | | |
| Address | | | | |
| City | Slate Zip | | | |
| Country | | | | |
| Telephone | Email | | | |
| tem the; Applicant/Inveπtor. | | | | |
| Assignee of record of the entire Interest. See 37 CFR | 3.74 | | | |
| Statement under 37 CFR 3,73(b) is enclosed. (Form | 70/\$B/96) | | | |
| SIGNATURE of | Applicant or Assignee of Record | | | |
| Signature Quarter McMaha | Date 11-6-2008 | | | |
| Name JENNIFER McMAHON Telephone 317-276-1543 | | | | |
| Title and Company Eli Lilly 9 Company | | | | |
| NOTE: Signatures of all the inventors or assignees of record of the Enti- signature is required, see below". | e interest or their representative(s) are required. Submit multiple forms if more than one | | | |
| *Total of forms are submitted, | | | | |
| agriculto o required; and decire; | e interest or their representative(s) are required. Submit multiple forms if more than one | | | |

This collection of information is required by 37 CFR 1.31, 1.32 and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gethering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form end/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Application Information

Application No.:: 10/599,010

Filing date:: 09/18/06

Application Type:: Regular (National Stage)

Subject Matter::

Suggested Classification::

None

Suggested Group Art Unit::

None

CD-ROM or CD-R?::

None

Number of CD disks::

None

Number of copies of CDs::

None

Sequence submission?:: None

Computer Readable Form?:: No

Number of Copies of CRF:: None

Title:: NOVEL PHARMACEUTICAL FORMS, AND METHODS

OF MAKING AND USING THE SAME

Attorney Docket Number:: TPI-5053C3XC1T

Request for Early Publication:: No Request for Non-Publication:: No

Suggested Drawing Figure:: None

Total Drawing Sheets:: 17

Small Entity?:: No

Petition included?:: No

Petition Type:: N/A

Secrecy Order in Parent Appl.?:: No

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Domestic Priority Information

| Application:: | Continuity Type:: | Parent Application:: | Parent Filing Date:: |
|-----------------------|--|--|---|
| This application is a | National Stage of | PCT/US2005/009305 | March 17, 2005 |
| PCT/US2005/009305 | An application claiming the benefit under 35 USC 119(e) of | 60/554,834 | March 19, 2004 |
| And And And | · , | 60/566,647 60/610,296 60/637,907 | April 30, 2004 September 16, 2004 December 21, 2004 |

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Frank C. Eisenschenk, Ph.D.

Reg. No. 45,332 July 29, 2011